

### **REMARKS**

Claims 1, 3-24, 26-30, 32, 36-47 and 49-56 are in the present application.

The Examiner has rejected claims 7 and 14, under the second paragraph of 35 USC §112, as being indefinite for two specifically stated reasons. The Examiner has objected to claim 7 for using the phrase “creating by a human” which is contended to be “so broad that it is not defined for its metes and bounds.” That phrase has been deleted from claim 7 and it is respectfully submitted that the rejection is no longer applicable to claim 7.

The Examiner has also objected to claim 14 based on the use of the phrase “distributing...upon a targeted area...in accordance with the charge on the material.” The Examiner contends that “it is unclear how the charge accords a specific distribution.” This objection is respectfully traversed. It is to be remembered that the claims of the present application require that the droplet particulates formed be, at least in part, charged. Once that is borne in mind, it is fairly easy to see how the charge on the droplets can create a distribution of droplets on the surface of the animal. Specifically, the charge on the droplets (i.e., the relative repulsion from droplet to droplet) causes a distribution of droplets on the surface based on repulsion of the charged particles with regard to each other, as well as attraction or repulsion to various charges on the surface at the target area. Accordingly, based on those factors, the particles will form a distribution on the target surface and that is what is intended to be encompassed by claim 14. One skilled in the art would have no trouble understanding that and, therefore, it is respectfully submitted that this rejection should be withdrawn.

The Examiner has also rejected all claims in the application under 35 USC §103(a), based upon the Coffee ‘517 and the Coffee ‘877 patents, in view of the Maget and Matthews patents. The Examiner has also cited other references, including Ramsey, Franklin, Sembo, and Dvorsky in various combinations with the two Coffee references and the Maget and Matthews patents in rejecting several other claims of the application. Since all of these rejections rely primarily on the two Coffee patents, they will all be considered together in this response.

By way of review, the present claims (claim 1 et seq) define a method for treating non-human animals by creating a quantity of charged particulates of a therapeutic agent adapted for transdermal delivery and then directing them toward the skin surface of the animal. The claims have been amended so as to require that the charged particulates formed be formed using electrohydrodynamic spray (EHD). It is taught that when this technique is used, effective spray on the skin surface can be achieved without causing the noise generally associated with mechanical spray devices thereby making the spray process easier with regard to the animal. Antecedent basis for this amendment is found in claim 2, among others, of the present application. Thus, it should be emphasized that claim 1 of the present application (and those dependent from it) require several specific things: i.e., that the particulates be charged, that they be adapted for transdermal delivery, and that the spray be made by an EHD process. Claims 23 et seq also envision the spraying of pesticides or cosmetic agents, in addition to transdermal therapeutic agents. Those claims require that the agents be sprayed on fur, feathers, scales or wool.

As the Examiner describes the references, the two Coffee patents teach an EHD aerosolization process for spray delivery of medicaments into the respiratory tract. The purpose of the Coffee '877 patent is to form uncharged droplets (the Dvorsky patent also cited by the Examiner specifically teaches that uncharged droplets should be used and, therefore, teaches away from the charged droplets required by the present application). The claims of the present application require that the droplets formed be charged. Further, neither of the Coffee references cited by the Examiner teaches the use of medicaments formulated for transdermal delivery; once again, this element is required by claims 1 and those dependent from it in the present application. Finally, neither reference teaches spray of a material onto fur, feathers, scales or wool.

The Maget patent teaches a self-contained aerosolization device which uses gas pressure to form and expel an aerosol. The disclosed procedure is not an EHD aerosolization process. It is taught that this device can be used to deliver parasiticidal liquids to animals and can also be used for transdermal delivery. The Maget device does not provide the charged particles which is also a required element of the present invention.

The Matthews patent teaches an automatic animal activated apparatus for spraying insecticides onto livestock (the device sprays one side of the animal at a time). The aerosol formed using air pressure and is not an EHD process. Further, charged particles are not formed by the device and the material sprays on the cattle is not delivered transdermally. In fact, since it is an insecticide, a user of the Matthews device would not want transdermal delivery to the animal.

Thus, neither Maget nor Matthews teaches either EHD aerosol formation or the use of charged particles, both of which are required elements of all claims of the present application. The Maget and Matthews patents disclose specific spray devices which are said to be particularly beneficial for their intended use. Other than through hindsight, there would have been no reason for one skilled in the art to ignore the beneficial spray devices taught in the Maget and Matthews patents and instead use an EHD device (which is not taught for transdermal delivery) to form charged particles for transdermal delivery. Thus, while one skilled in the art could find individual elements of the present claims in the Coffee patents and the Maget and Matthews patents, there would have been no reason at all, other than through hindsight, for that person to combine those elements in order to form the present invention.

The other references cited by the Examiner do nothing to supplement these deficient disclosures. Specifically, the Ramsey patent teaches a device for washing livestock prior to slaughter. A detergent solution is utilized and that solution may include an antiparasitic agent. Once again, the spray technique utilized in Ramsey is not EHD and it does not form charged particles. Further, the solution sprayed onto the cattle is clearly not intended for transdermal delivery.

The Franklin patent discloses a terpene-based pesticide solution (for example, to combat lice) which can be sprayed onto humans or animals using, for example, a pump spray. Once again, the spray technique is not EHD and does not form the charged particles required by the present claims. Further, because they are pesticides, the solutions sprayed in the Franklin patent are not intended for transdermal delivery.

The Sembo patent discloses specific formulations for the control of ectoparasites in animals (for example, fleas) which are applied topically to the animal and can be sprayed. Once again, EHD is not a disclosed technique and the material applied in the Sembo patent is not applied as charged particles. Again, since the formulations are antiparasitics, they are not intended for transdermal delivery and, in fact, transdermal delivery would probably not be desired for an antiparasitic agent designed to be used on the skin surface.

The Dvorsky patent discloses a device for forming aerosols by EHD. Not only is the entire purpose of this device to form discharged particles, the Dvorsky patent specifically teaches that non-charged droplets are preferred for therapeutic use (see column 1, lines 48-52). Therefore, the Dvorsky patent actually teaches away from the charged particles required in the present claims. The Dvorsky patent also does not teach transdermal delivery of a pharmaceutical substance.

Therefore, the two Coffee references cited by the Examiner do not teach the use of a pharmaceutical active formulated for transdermal delivery. In fact, those references teach application by inhalation. In addition, both the '877 Coffee and the Dvorsky patent specifically teach away from the use of the charged particles required in the present application. The Maget, Matthews and Ramsey patents all teach very specific devices for spraying pesticidal material onto animal skin. Since the sprayed materials are pesticides, the last thing that the user would want would be for those materials to be delivered transdermally (i.e., one would not want the pesticides to penetrate the skin and get into the bloodstream of the animals). Further, each of these three patents teach very specific devices which are taught to be beneficial for use in applying materials to animals. One skilled in the art would have had no reason to abandon these beneficial apparatuses in order to use EHD for that purpose and no such reason is given, other than hindsight. Accordingly, it is respectfully submitted, that the rejection under 35 USC §103(a) is not applicable to the currently pending claims, as amended herein, and is respectfully requested that it be withdrawn.

In this regard, claim 12 should also be pointed out. This claim defines the benefit of the present invention which allows for a targeted spray of agents, such as transdermally deliverable

medicinal agents, to an animal without requiring the noise which generally accompanies the use of conventional mechanical sprayers, such as those taught in the Maget, Matthews or Ramsey patents. The ability to provide this spray quietly and not frighten the animals is a major benefit of the present invention and it is embodied in claim 12.

Finally, the Examiner has rejected the claims of the present application, based on obviousness-type double patenting over the following patents: US Patent 5,655,517; US Patent 5,813,614; US Patent 5,915,377; US Patent 6,105,877; US Patent 6,252,129; US Patent 6,386,195; or US Patent 6,595,208. The Examiner has combined each of these patents individually with the teachings of the '517 Coffee patent, the '877 Coffee patent, the Maget patent, the Matthews patent, the Ramsey patent, the Franklin patent, the Sembo patent and the Dvorsky patent, all of which were discussed above.

None of the patents which are the primary focus of the double patenting rejection claim the present invention or even anything similar to the present invention. US Patent 5,655,517 describes a specific EHD device; there is absolutely no suggestion in that reference or in any of the other references cited by the Examiner to provide transdermal delivery of a medicament material. Similarly, US Patent 5,813,614 defines a specific EHD device which forms discharged particles. The claims of the present invention require charged particles and the reference does not in any way suggest the use of transdermal delivery of a medicament. US Patent 5,915,377 also describes a specific EHD device which incorporates multiple comminution sites for mixing particle charges. Again, this patent does not in any way suggest the formation of a medicament into an aerosol for transdermal delivery, which is a required element of the present claims. US Patent 6,105,877 also discloses a specific EHD device for forming uncharged particles. This, in fact, teaches away from the claims of the present invention which require the use of charged particles. US Patent 6,252,129 describes a device for forming at least partially solid materials by EHD, for example, to form a wound dressing. This has absolutely nothing to do with the charged liquid droplets which are formed in the present invention and are used for transdermal delivery. US Patent 6,386,195 also claims a specific EHD device which forms discharged particles, rather than the charged particles which are required elements of the presently claimed

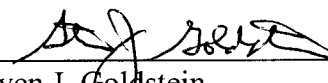
invention (once again, transdermal delivery is also not suggested). Finally, US Patent 6,595,208 describes a specific EHD device to form discharged particles. Once again, the present claimed invention requires charged particles as well as the delivery of medicament transdermally, which is not in any way taught in the claims of the '208 patent.

In view of this, claims of the present application are different from and clearly not obvious over the claims of the seven patents cited by the Examiner. Accordingly, it is respectfully requested that the obviousness-type double patenting rejection be withdrawn.

In light of the foregoing, it is respectfully submitted that the claims currently pending in the present application, as amended herein, are now in form for allowance. Accordingly, reconsideration and allowance of those claims are earnestly solicited.

Respectfully submitted,  
Brian Graham et al.

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Date

by:   
Steven J. Goldstein  
Registration No. 28,079  
FROST BROWN TODD LLC  
2200 PNC Center  
201 East Fifth Street  
Cincinnati, Ohio 45202-4182  
Telephone (513) 651-6131